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In the Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-501

WYETH LABORATORIES, a Division of American Home Products Corporation, a Delaware corporation,

Petitioner,

vs.

EPIFANIO REYES, Individually and as next friend of Anita Reyes, a minor,

Respondent.

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

The American Academy of Pediatrics respectfully moves the Court for leave to file the attached brief *amicus curiae* in support of the petition for a writ of certiorari filed by petitioner Wyeth Laboratories, a division of American Home Products Corporation. The consent of the attorney for the petitioner has been obtained. The consent of the attorney for the respondent was requested but refused.

The American Academy of Pediatrics is a not-for-profit scientific and educational organization. The over-all objective of the Academy is to maximize the quality and quan-

tity of medical care available to children. Membership in the Academy is limited to certified pediatricians possessing at least five years specialized practice in pediatrics.

The Academy, through its Committee on Infectious Diseases, has supported the development of safe, effective immunization programs for many years. In performing this work the Academy frequently has acted at the instance of, or in cooperation with, the United States Government. Of vital interest to the Academy has been the prevention and control of poliomyelitis through public participation in immunization programs.

The Academy seeks leave to file a brief *amicus curiae* which discusses the effects of the decision of the court below upon immunization programs operated by public health authorities to prevent the spread of infectious disease among children. The Academy firmly believes that the decision of the court below requiring a manufacturer to warn vaccine recipients in a state public health program of remote, isolated risks thwarts a strong public policy favoring universal participation in immunization programs to eliminate infectious disease among children.

Respectfully submitted,

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November 27, 1974

In the Supreme Court of the United States

OCTOBER TERM, 1974

NO. 74-501

WYETH LABORATORIES, a Division of American Home Products Corporation, a Delaware corporation,

Petitioner,

vs.

EPIFANIO REYES, Individually and as next friend of Anita Reyes, a minor,

Respondent.

BRIEF AMICUS CURIAE OF THE AMERICAN ACADEMY OF PEDIATRICS IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

Amicus curiae, the American Academy of Pediatrics, supports the petition of Wyeth Laboratories that a writ of certiorari issue to review the opinion and judgment of the United States Court of Appeals for the Fifth Circuit rendered in these proceedings on July 31, 1974.

Question Presented

Whether a judicially created rule requiring a manufacturer to warn vaccine recipients in a state public health program of remote, isolated risks contravenes a strong public policy favoring universal participation in immunization programs to eliminate infectious disease among children.

Statement of the Case

The Academy adopts the Statement of the Case set forth at pp. 6-7 of the Petition for Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit of Wyeth Laboratories, filed October 29, 1974.

REASONS FOR GRANTING THE WRIT

A JUDICIALLY-CREATED RULE REQUIRING A MANUFACTURER TO WARN VACCINE RECIPIENTS IN A STATE PUBLIC HEALTH PROGRAM OF REMOTE, ISOLATED RISKS THWARTS A STRONG PUBLIC POLICY FAVORING UNIVERSAL PARTICIPATION IN IMMUNIZATION PROGRAMS TO ELIMINATE INFECTIOUS DISEASE AMONG CHILDREN.

The United States in recent years has enjoyed extraordinary reductions in morbidity and mortality from many infectious diseases. Remarkable decreases in death rates from whooping cough, diphtheria and tetanus have been recorded. Smallpox has been absent for nearly a quarter of a century. Measles has become sufficiently uncommon that most young physicians have not seen a case, and its disastrous complication, encephalitis, is extremely rare. Recent programs directed at preventing German measles in women early in pregnancy have reduced infant death and disability significantly. Poliomyelitis has all but disappeared from this country.

This remarkable freedom from these serious infectious diseases was achieved through the nationwide concerted efforts of many groups. The United States Public Health Service, state and local health departments, the private sector of medicine, scientific investigators, pharmaceutical manufacturers and medical organizations such as the American Academy of Pediatrics and the American Public Health Association—each played a significant role in the fight against infectious disease. Reflecting the public interest in winning this fight, state law-making bodies have also entered the battle.

The Texas legislature has required by statute that all children be immunized against poliomyelitis, rubella, diphtheria, rubeola, tetanus, and smallpox before entering elementary school. 67 Texas Rev. Stat. §2.09(a) (1971). The Texas legislature has also required that the State Department of Public Health should provide the required immunizations to children where there is no local provision for such services. 67 Texas Rev. Stat. §2.09(d) (1971). These provisions of Texas law evidence a strong public policy favoring universal participation in immunization programs to combat infectious disease.

A ruling by the Federal courts requiring a manufacturer to warn vaccine recipients in a state public health program of remote, isolated risks would contravene this policy. For Texas school children who are required to take the vaccine the warning would be superfluous since they have no choice in the matter under state law. For other citizens of Texas and for citizens of other states which permit individual choice in the matter, the warning would discourage many persons from taking the vaccine with the potentially adverse consequences—both to the individual and to the community—discussed below.

A simple statement that ingestion of the Sabin vaccine might infrequently transmit polio to the vaccine recipient would actually mislead the potential recipient by focusing on the remote risk of taking the vaccine while ignoring the far greater risk, associated with not taking the vaccine, of remaining susceptible to the polio virus. If a person's consent to taking the vaccine is to be truly "informed", a warning must convey to him the relative risks of contracting polio with and without the vaccine. The difficulty lies in framing such a warning that will adequately convey to the potential recipient the relative risks, which will be comprehensible to all persons who must take the vaccine,

and which will not unduly frighten potential recipients so as to weaken immunization programs.

Even for the expert the relative risks of contracting polio associated with taking and not taking the vaccine are difficult to quantify because they are derived from projections, epidemiologic interpretation, and statistical understanding. To describe adequately the relative risks would require a complex statement that many people would not understand or which might frighten away potential recipients. Experiments have shown that as information imparted with respect to a drug becomes more detailed and complex, the potential recipient's comprehension of the information declines and fewer people are willing to take the drug. L. Epstein and L. Lasagna, "Obtaining Informed Consent", 123 Archives of Internal Medicine 682 (June 1969).

The danger of confusing and frightening away potential recipients of the Sabin vaccine is heightened where the warning is to be communicated directly by the drug manufacturer to the ultimate recipient. Ordinarily, the courts have required that a prescription drug manufacturer communicate warnings only to the health professional prescribing the drug. E.g., *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). This rule has the practical advantage of laying the responsibility of communicating the warning to the patient on the health professional with whom the patient has immediate contact. The health professional enjoys the advantage of being able to tailor warnings given to the patient so as to fit the patient's capacity for understanding and so as to minimize undue fears in the patient. Furthermore, he probably enjoys the patient's respect for his judgment, possibly as the result of a long-term relationship or simply because the patient has sought him out. The manufacturer, most likely physically as well as psychologically distant, does not enjoy comparable ad-

vantages. In order to convey a warning the manufacturer must necessarily resort to impersonal techniques such as a printed consent to be signed by the recipient of the vaccine. The language of such a consent cannot be adjusted to meet the individual patient's capacity for comprehension or to allay his undue fears.

The requirement of a warning directly from the manufacturer to the recipient would inevitably confuse and frighten at least a portion of the public and would decrease by a significant number the percentage of people immunized. Such a decline would portend new outbreaks of infectious disease such as polio. With the exception of smallpox the infectious agents responsible for these illnesses are ever present in this country. Relaxation of immunization efforts can only result in a renewed outbreak of one or more of these diseases. Indeed, some complacency resulting from the striking reduction in disease rates was associated with diminished rates of satisfactory immunization against these diseases in the past few years, as evidenced in isolated outbreaks of diphtheria, measles and poliomyelitis in 1970. Increased emphasis on immunization programs subsequently resulted in lower infection rates in 1971.

Recognizing that even the slightest relaxation in the battle against infectious disease could be disastrous, the State of Texas has embarked on a course aiming at universal immunization. It has required that all school children be immunized against certain infectious diseases, including polio, and it has directed the State Department of Public Health to make these vaccines available to the public. The courts should be wary of upsetting this laudable legislative goal by requiring a warning from the manufacturer of the drug to the recipient which would have the effect of confusing and frightening the potential recipient.

Without in any way commenting on the particular facts of the case at bar, the American Academy of Pediatrics recognizes the very remote risk of a person contracting polio as a consequence of receiving a polio vaccine. However infinitesimal the number of such cases, the Academy strongly supports efforts to eliminate these cases entirely. In addition, the Academy urges legislative consideration of public programs to provide for the care of the few people who contract polio from the vaccine. But the Academy strongly believes that informed medical experience has demonstrated conclusively that the only efficacious way of eliminating risks of diseases such as poliomyelitis has been pursuant to immunization programs, which can only be effective if backed by state legislation and which ought not to be weakened by a judicially-created rule.

If this Court denies the petition for a writ of certiorari and the award to plaintiff in this case is sustained, the manufacturer will be required to warn directly each potential recipient of the vaccine. The inevitable result will be that fewer people will seek immunization. It would be a most tragic irony if the courts, in striving to help one victim, were by that very act to add to the ranks of victims of infectious disease.

CONCLUSION

For the reasons stated, a writ of certiorari should be granted to review the judgment and opinion of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

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